# **EXHIBIT A**

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

| JANSSEN PHARMACEUTICA N.V.,  | ) |                     |
|------------------------------|---|---------------------|
| JANSSEN, L.P., and           | ) |                     |
| SYNAPTECH, INC.,             | ) |                     |
|                              | ) |                     |
| Plaintiffs,                  | ) |                     |
|                              | ) |                     |
| v.                           | ) | C.A. No. 05-371-KA. |
|                              | ) |                     |
| MYLAN PHARMACEUTICALS INC.   | ) |                     |
| and MYLAN LABORATORIES INC., | ) |                     |
|                              | ) |                     |
| Defendants.                  | ) |                     |

#### PLAINTIFFS' FIRST SET OF REQUESTS FOR DOCUMENTS AND THINGS

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, "Janssen"), and Synaptech, Inc. (collectively, "Plaintiffs") hereby request that Defendants Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. ("Mylan") respond to the following requests for production within thirty (30) days after service, in accordance with the Definitions and Instructions below. Documents should be produced at the law offices of Covington & Burling, 1201 Pennsylvania Avenue, NW, Washington, District of Columbia 20004.

#### **DEFINITIONS AND INSTRUCTIONS**

"Janssen" shall mean Plaintiff Janssen Pharmaceutica N.V. and Janssen
 L.P. and all of Janssen Pharmaceutica N.V.'s and Janssen L.P.'s corporate parents,
 corporate predecessors and past or present subsidiaries, affiliates, divisions, departments,
 officers, directors, principals, agents and employees.

- 3. "Patent-In-Suit" shall mean United States Patent No. 4,663,318 ("the '318 patent"), and/or any foreign counterpart to that patent.
- 4. "Complaint," "Answer," "Affirmative Defense," "Reply" and "Counterclaim" shall mean as originally filed or as amended or supplemented throughout the progression of the case.
- original is unavailable) and each non-identical copy (where different from the original because of notes made on the copy or otherwise) of any writing or record, including but not limited to all written, typewritten, handwritten, printed or graphic matter of any kind or nature, however produced or reproduced, any form of collected data for use with electronic data processing equipment, and any mechanical or electronic visual or sound recordings, including, without limitation, all tapes and discs, now or formerly in your possession, custody or control, including all documents as defined in the broadest sense permitted by the Federal Rules of Civil Procedure. The term "document" includes, but is not limited to, e-mails, invoices, purchase orders, checks, receipts, letters and other correspondence, offers, contracts, agreements, bids, proposals, licenses, permits, reports to government agencies, ledgers, accounts receivable, accounts payable, account statements, financial statements, monthly reports, other reports, minutes of meetings,

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sales estimates, sales reports, memoranda, notes, calendar or diary entries, agendas, bulletins, graphs, charts, maps, photographs, drawings, surveys, data, price lists, summaries, telegrams, teletypes, computer printouts, magnetic tapes, discs, microfilm, and microfiche.

- 6. Documents that are in paper form or that constitute other physical objects from which recorded information may be visually read, as well as audio or video tapes and similar recordings, should be produced in their original form or in copies that are exact duplicates of the originals. Computer files and similar electronic records should be produced in a readable form mutually agreed upon by the parties. Plaintiffs encourage Defendants to consult with them in advance before producing any such records so that a suitable mutually agreeable form of production may be identified.
- 7. "Communication" means any transmission of information by one or more persons and/or between two or more persons by means including telephone conversations, letters, telegrams, teletypes, telexes, telecopies, electronic mail, other computer linkups, written memoranda, and face-to-face conversations.
- 8. "Relate to," "relates to," "refer to," or "concerning" means mentioning, discussing, reflecting, containing, embodying, stating, dealing with, or making reference to or relating to in any way.
- 9. "Dementia of the Alzheimer's type" means any diagnosis, illness, or ailment described as being of the Alzheimer's type, including without limitation Senile Dementia of the Alzheimer's Type, Alzheimer's Dementia, and/or Alzheimer's Disease.
- 10. The words "and" and "or" shall be construed conjunctively or disjunctively as necessary to make the request inclusive rather than exclusive.

- If Defendants object to any portion of any request, they should identify the 11. portion to which they object and respond to the remainder.
- Documents should be produced either (a) as they are kept in the ordinary 12. course of business, complete with the original file folders, binders, or other containers in which they are stored (or legible copies of the labels from those folders, binders, or containers), or (b) organized according to the document request(s) to which they are responsive. If Mylan elects the latter mode of production, each document or set of documents from a particular file, binder, or other container should be accompanied by a legible copy of the label from that container or some other reliable indicator of the file from which it was taken.
- If Mylan asserts a claim of privilege as to one or more documents sought 13. in this request, Mylan should list, for each such document, the document's date, signatory or signatories, author(s), addressee(s), each other person who received a copy, the subject matter of the document, its location and custodian, and the basis for the claim of privilege. Such information should be supplied in sufficient detail to permit Plaintiffs to assess the applicability of the privilege claimed.
- 14. If any of the requested documents was but is no longer in Defendants' possession or subject to its control, state what disposition was made of it and when.
- 15. This request is deemed continuing, and it is requested that supplemental responses and production be provided as additional documents become available, in accordance with Federal Rules of Civil Procedure 26(e).

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#### **REQUESTS FOR PRODUCTION**

- 1. All documents that relate to your responses or to which you refer in responding to Plaintiffs' interrogatories.
- 2. All documents referenced in your Initial Disclosures produced in accordance with Fed. R. Civ. P. 26(a)(1).
- 3. All documents relating to any ANDA (including without limitation Mylan's Abbreviated New Drug Application ("ANDA") No. 77-590), and any amendment, supplemental filing, or addition thereto, submitted by you or on your behalf to the FDA seeking permission to manufacture, market, or sell a drug product containing galantamine or any salt thereof, including without limitation:
  - a. documents relating to the history and status of any application for approval by FDA of a drug product containing galantamine or any salt thereof, including without limitation any ANDA filed by or for Mylan for such a product and all documents related thereto, including ANDA amendments, supplements, deficiency letters, tentative approval letters, and final approval letters;
  - b. documents relating to any communication, correspondence, or contact with the FDA by you concerning each such ANDA, and any amendment, supplemental filing, or addition thereto, including but not limited to letters, emails, teleconference minutes, notes, and meeting minutes from discussions held with and between you and the FDA;

- C. documents relating to the prosecution of each such ANDA, including but not limited to internal meeting minutes, notes, internal correspondence, draft submissions, and plans;
- d. documents relating to the decision to file, the steps taken to prepare, and the timing of the submission of each such ANDA or any of the documents or information contained therein;
- documents relating to any difficulties, problems, or delays in e. obtaining FDA approval for any such ANDA; and
- f. a complete copy of the Drug Master File referenced in each such ANDA.
- 4. All documents relating to research and development of any drug product containing galantamine or any salt thereof, including but not limited to laboratory notebooks, invention disclosure forms, research plans, summaries or proposals, compilations of data or data summaries, research protocols, presentations or status reports, meeting minutes, scientific publications, and agreements with third parties concerning research and development of drug products containing galantamine or any salt thereof.
- 5. All documents relating to research, analysis, or evaluation for any purpose of a drug product containing galantamine or any salt thereof, including without limitation laboratory notebooks, invention disclosure forms, research plans, summaries or proposals, compilations of data or data summaries, research protocols, presentations or

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status reports, meeting minutes, scientific publications, and agreements with third parties concerning your research, analysis or evaluation.

- 6. All documents relating to the market or potential market for drug products containing galantamine or any salt thereof, including but not limited to Mylan's proposed galantamine hydrobromide products. Such documents include marketing analyses, business plans, sales projections, market research or surveys, and sales information relating to current galantamine hydrobromide products.
- 7. All documents relating to Mylan's decision to make and sell a drug product containing galantamine or any salt thereof.
- 8. All documents that relate to any application filed with any governmental agency or regulatory body, whether foreign or domestic, seeking approval to manufacture, market or test a drug product containing galantamine or any salt thereof.
- 9. All documents relating to the types of conditions or indications for which physicians may prescribe a drug product containing galantamine or any salt thereof, and the factors that might influence a physician's decision with respect to whether to prescribe one of these products or any other product for any such condition, including the role of efficacy, side effects, price, brand name, and patents.
- 10. All documents relating to research and development of any drug product intended to treat dementia of the Alzheimer's type, including but not limited to laboratory notebooks, invention disclosure forms, research plans, summaries or proposals, compilations of data or data summaries, research protocols, presentations or status

reports, meeting minutes, scientific publications, and agreements with third parties concerning research and development of drug products intended to treat dementia of the Alzheimer's type.

- 11. All documents relating to research, analysis, or evaluation for any purpose of a drug product intended to treat dementia of the Alzheimer's type, including without limitation laboratory notebooks, invention disclosure forms, research plans, summaries or proposals, compilations of data or data summaries, research protocols, presentations or status reports, meeting minutes, scientific publications, and agreements with third parties concerning your research, analysis or evaluation.
- 12. All documents relating to the market or potential market for drug products intended to treat dementia of the Alzheimer's type. Such documents include marketing analyses, business plans, sales projections, market research or surveys, and sales information relating to current drug products intended to treat dementia of the Alzheimer's type.
- 13. All documents relating to Mylan's decision to make and sell a drug product intended to treat dementia of the Alzheimer's type.
- All documents that relate to any application filed with any governmental 14. agency or regulatory body, whether foreign or domestic, seeking approval to manufacture, market or test a drug product intended to treat dementia of the Alzheimer's type.

- 15. All documents relating to the types of conditions or indications for which physicians may prescribe a drug product approved for the treatment of dementia of the Alzheimer's type, and the factors that might influence a physician's decision with respect to whether to prescribe one of these products or any other product for any such condition, including the role of efficacy, side effects, price, brand name, and patents.
- 16. All documents relating to Mylan's April 27, 2005 Notice of Paragraph IV Certification to Janssen Pharamaceutica N.V., Janssen Pharamaceutica Products, L.P., and Synaptech, Inc. (hereinafter "Mylan's Paragraph IV Certification").
- 17. All documents relating to the analysis or evaluation for any purpose of any drug product containing galantamine or any salt thereof, including but not limited to Janssen's RAZADYNE®/REMINYL® products.
- 18. All documents relating Mylan's contention that Plaintiffs have not accurately characterized or described the labeling of proposed galantamine hydrobromide tablets and REMINYL® and RAZADYNE® tablets. (Mylan's Answers, ¶23, 24).
- 19. Documents, including corporate organizational charts and/or handbooks sufficient to show Mylan's management structure from one year prior to the decision to develop and sell a drug product containing galantamine or any salt thereof to the present.
  - 20. All documents relating to the '318 patent, including without limitation:
    - a. any evaluation, analysis, or discussion relating to the '318 patent;

- any communications between Mylan and any third party b. concerning the '318 patent.
- All documents relating to any patent or patent application filed by or for 21. Mylan or assigned to Mylan describing or claiming a drug product containing galantamine or any salt thereof.
- All documents relating to any patent or patent application filed by or for 22. Mylan or assigned to Mylan describing or claiming any treatment for dementia of the Alzheimer's type, including without limitation any drug product intended for the treatment of dementia of the Alzheimer's type.
- All documents relating to anything that Mylan contends is "prior art" to 23. the '318 patent.
- All documents relating to Mylan's contention that the '318 patent is 24. invalid.
- All documents relating to Mylan's contention that Mylan's proposed 25. galantamine hydrobromide products do not infringe Janssen's RAZADYNE®/REMINYL® products.
- All documents relating to Mylan's third affirmative defense that the 26. United States District Court for the District of Delaware lacks personal jurisdiction over Mylan Laboratories.

- 27. All documents relating to Mylan Laboratories' contacts with or presence in the State of Delaware.
- 28. Documents sufficient to show, on a monthly basis, sales of drug products manufactured or sold by Mylan in the State of Delaware, including the number of units sold, price (including any credits, discounts, and rebates), revenues, costs (including, but not limited to, development, labor, material, ingredient, distribution, manufacturing, marketing, and advertising costs) and profits net of all costs and taxes.
- 29. Documents sufficient to show all past and current customers of drug products manufactured or sold by Mylan in the State of Delaware including without limitation:
  - a. the identity of each customer;
  - b. the date of each sale;
  - c. the package size, dosage form, and quantities purchased by each customer;
  - d. the per unit price charged to each customer;
  - e. all credits, discounts, rebates, or other concessions to the price in connection with the sale of these products to each customer;
- 30. All documents relating to contracts, agreements, or arrangements with any customer in the State of Delaware relating to the sale of drug products manufactured or sold by Mylan, including but not limited to offers or solicitations for sale, quotes, orders,

and documents sufficient to show any credits, discounts, rebates, or other concessions in connection with the sale of such products.

- All documents relating to Mylan's fourth defense that Mylan Laboratories 31. is not a proper party to this action.
- All documents relating to Mylan's fifth defense that the Complaint fails to 32. state a claim upon which relief can be granted.
- All documents relating to Mylan's sixth defense that the Plaintiff's willful 33. infringement claims fails to state a claim upon which relief can be granted.
- To the extent not otherwise encompassed by other document requests, 34. produce all documents relating to Mylan's affirmative defenses and counterclaims in this case.
- All documents relating to document retention or destruction at Mylan from 35. one year prior to the decision to develop and sell a galantamine hydrobromide product to the present.

#### **ASHBY & GEDDES**

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Dated: September 9, 2005

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#### **CERTIFICATE OF SERVICE**

I hereby certify that on the 9<sup>th</sup> day of September, 2005, the attached PLAINTIFFS'

### FIRST SET OF REQUESTS FOR DOCUMENTS AND THINGS was served upon the

below-named counsel of record at the address and in the manner indicated:

Mary B. Matterer, Esquire Morris James Hitchens & Williams LLP 222 Delaware Avenue, 10<sup>th</sup> Floor Wilmington, DE 19801 HAND DELIVERY

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